



## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2023-0455; FRL-11520-01-OCSP]**

**RIN 2070-ZA16**

### **L-lactic Acid; Proposed Tolerance Actions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to remove a duplicative exemption from the requirement of a tolerance for residues of L-lactic acid, herein referred to as lactic acid, when applied to dairy-processing equipment and food-processing equipment and utensils. In addition, the Agency is proposing to establish exemptions from the requirement of a tolerance for residues of lactic acid when used as a fruit and vegetable wash in or on all raw agricultural commodities, and for indirect or inadvertent residues of lactic acid in or on all livestock commodities, when residues are present therein as a result of animal drinking water coming into contact with hard non-porous surfaces treated with lactic acid (i.e., troughs). This rulemaking is proposed on the Agency's own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA), in order to implement the tolerance actions EPA identified during its review of this chemical as part of the Agency's registration review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

**DATES:** Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2023-0455, by one of the following methods:

• *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Anita Pease, Antimicrobials Division 7510M, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: 202-566-0736; email address: [pease.anita@epa.gov](mailto:pease.anita@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

*B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/comments.html>.

## **II. Background**

*A. What Action is the Agency Taking?*

EPA is proposing the following tolerance actions related to lactic acid:

- To remove the duplicative exemption from the requirement of a tolerance under 40 CFR 180.940(b) for residues of lactic acid when applied to dairy-processing equipment and food-processing equipment and utensils, as these use sites are covered by the exemption under 40 CFR 180.940(a) (i.e., food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils).
- To establish exemptions from the requirement of a tolerance under 40 CFR 180.1090 for residues of lactic acid when used as a fruit and vegetable wash in or on all raw agricultural commodities, and for indirect or inadvertent residues of lactic acid in or on all livestock commodities, when residues are present therein as a result of animal drinking water coming into contact with hard non-porous surfaces treated with lactic acid (i.e., troughs). EPA is proposing these exemptions to cover residues of lactic acid that may be found in food as a result of these uses.

EPA is proposing these tolerance actions to implement the changes identified as necessary during the registration review process to cover these pesticide chemical

residues when used in antimicrobial formulations consistent with current label use directions. Registration review documents, such as the draft risk assessment, typically identify certain tolerance actions, including modifications to reflect current use patterns, meet safety findings, and change commodity names and groupings, that may be necessary or appropriate to cover pesticide chemical residues or reflect current EPA policy.

For the pesticide chemical at issue in this rulemaking, EPA issued the *L-lactic Acid Combined Preliminary Work Plan and Proposed Interim Registration Review Decision* (Lactic Acid PWP/PID) in April 2021, and the *L-lactic Acid Interim Registration Review Decision* (Lactic Acid ID) in September 2021, as part of the second round of registration review for lactic acid. Electronic copies of the Lactic Acid PWP/PID, Lactic Acid ID, and other documents are available in docket ID number EPA-HQ-OPP-2020-0552 at <https://www.regulations.gov>. These documents contain a summary of the Agency's assessment of the potential risk associated with current product uses, and the Lactic Acid ID identified the need for the tolerance actions described above.

*B. What is the Agency's Authority for Taking this Action?*

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, authorizes the establishment, modification, and revocation of tolerances and exemptions from the requirement of a tolerance for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Residues of pesticides in or on food that are not covered by a tolerance or exemption are deemed unsafe under FFDCA section 408(a), 21 U.S.C. 346a(a), and any food containing unsafe residues is considered adulterated under FFDCA section 402(a), 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce, 21 U.S.C. 331(a). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under FIFRA, 7 U.S.C. 136 *et*

*seq.* Residues of food-use pesticides not registered in the United States must also be covered by a U.S. tolerance or exemption in order for commodities treated with those pesticides to be imported into the United States.

Section 408(c)(1)(B) of the FFDCA authorizes EPA to establish, modify, or revoke an exemption from the requirement of a tolerance on its own initiative, 21 U.S.C. 346(c)(e)(1)(B)). Before issuing a final regulation, EPA is required to issue a proposed rulemaking and provide a comment period. *Id.* 346(a)(e)(2).

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of a tolerance only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of the FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” 21 U.S.C. 346a(c)(2)(A)(ii). This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(c)(2)(B) of the FFDCA requires EPA, when making a safety determination concerning an exemption, to take into account, among other relevant considerations, those listed in section 408(b)(2)(C) and (D) of the FFDCA. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Section 408(b)(2)(D) identifies various factors, including available information on aggregate and cumulative exposure, for EPA consideration in making a safety determination.

### *C. When Do These Actions Become Effective?*

EPA is proposing that these tolerance actions become effective on the date of publication of the final rule in the **Federal Register**.

### **III. Proposed Rule**

EPA is proposing this rule to implement the tolerance actions identified in the September 2021, Lactic Acid ID. As noted in the Lactic Acid ID, there is an exemption from the requirement of a tolerance under 40 CFR 180.940(b) for residues of lactic acid when applied to dairy-processing equipment and food-processing equipment and utensils, with the limitation that the end-use concentration of lactic acid does not exceed 138 parts per million (ppm). During registration review, EPA determined that this exemption is duplicative of another exemption under 40 CFR 180.940(a) for residues of lactic acid when applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils, with the limitation that the end-use concentration of lactic acid does not exceed 10,000 ppm. EPA, on its own initiative, is therefore proposing to remove the duplicative exemption for lactic acid under 40 CFR 180.940(b).

As noted in the Lactic Acid ID, products containing lactic acid are registered for antimicrobial use as disinfectants, indirect food contact surface sanitizers, fungicides, and virucides. These products can be used for hard non-porous surfaces and in laundry machines; agricultural premises and equipment; food handling storage establishments, premises, and equipment; commercial, institutional, and industrial premises and equipment; fruit and vegetable treatment; human drinking water systems; and storage tanks. During registration review, EPA determined that residues of lactic acid may be present in or on raw agricultural commodities as result of its use as a fruit and vegetable wash. EPA also determined that lactic acid residues may be present in livestock commodities as a result of animal drinking water coming into contact with hard non-porous surfaces treated with lactic acid (i.e., troughs). The Agency currently does not have data to demonstrate that there is no reasonable expectation of residues in livestock commodities. Moreover, lactic acid is ubiquitous in the environment and occurs naturally

in certain foods, such as meat and dairy products, making it difficult to distinguish lactic acid residues resulting from animal drinking water versus other sources. EPA, on its own initiative, therefore proposes to establish exemptions from the requirement of a tolerance to cover residues of lactic acid in or on all raw agricultural commodities that may result from its use as a fruit and vegetable wash, and to cover indirect or inadvertent residues of lactic acid in or on all livestock commodities that may result from animal drinking water coming into contact with hard non-porous surfaces treated with lactic acid (i.e., troughs).

In order to establish tolerances or exemptions from the requirement of a tolerance, EPA is required to determine that each tolerance or exemption meets the safety standard of the FFDCA. In the Lactic Acid ID and other supporting documents referenced in this proposed rule, EPA considered the potential risks from exposure to lactic acid from registered uses and concluded that those uses did not present risks of concern.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure to support the establishment of exemptions from the requirement of a tolerance for residues of lactic acid proposed by this action.

The Agency relied on the most current science policies and risk assessment information in support of the registration review of lactic acid from the initial round of registration review. In addition, the Agency considered whether any new data requirements promulgated since the initial round of registration review warranted the requirement of additional data for this round of registration review. Based on available data considered in the initial round of registration review, the lack of toxicity, and low exposure levels expected from registered uses, the Agency determined there was no need

for new data or a new human health risk assessment. EPA's assessment of exposures and risks associated with lactic acid follows.

#### *A. Toxicological Profile*

EPA evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The toxicity profile of lactic acid indicates no significant systemic toxicity even at high dose levels. Specific information on the studies received and the nature of the adverse effects caused by lactic acid from the toxicity studies can be found in the June 2009 document *L-Lactic Acid Final Registration Review Decision*, which is available in docket ID number EPA-HQ-OPP-2008-0383 at <https://www.regulations.gov>.

#### *B. Toxicological Points of Departure/Levels of Concern*

Based on the low toxicity of lactic acid, the Agency determined that a quantitative human health risk assessment was not necessary, and no human health toxicity endpoints for lactic acid were selected.

#### *C. Exposure Assessment*

*Dietary exposure (food and drinking water).* Dietary exposures may occur from use of lactic acid as an active ingredient on food contact surfaces, treatment of fruits and vegetables, possibly in livestock commodities, and from exposure in human drinking water systems. Dietary exposure may also occur from the use of lactic acid as an inert ingredient in pesticide formulations applied to growing crops and to plants after harvest or in antimicrobial formulations applied to food-contact surfaces. In addition, the U.S. Food and Drug Administration (FDA) has approved the use of lactic acid as a food additive at levels up to 138 ppm in sanitizing solutions, which is another source of dietary exposure. While an exemption from the requirement of a tolerance has been established



for lactic acid when used as a plant growth regulator, there are no products currently registered by EPA for the plant growth regulator outdoor use pattern. Dietary exposure is not expected from use of lactic acid in mosquito control end-use products, as they are used in traps. Lactic acid occurs naturally in fruit, the soil, and the bloodstreams of animals, and is added to many foods such as beer and fermented milk products. It is generally recognized as safe by FDA. Because of the low toxicity associated with lactic acid, EPA concluded that dietary exposure through food and drinking water will not pose a risk of concern. Therefore, EPA determined that dietary and drinking water exposures and risks do not need to be quantitatively assessed for lactic acid.

*Non-dietary (residential) exposure.* Based on the registered uses of lactic acid as an indirect food-contact sanitizer, disinfectant, and in indoor/outdoor traps for mosquitoes, there is potential for residential dermal, inhalation and incidental oral exposure. Exposures and risk as a result of the registered uses of lactic acid are expected to be minimal on the basis of the current label restrictions and precautionary statements, the low concentration of active ingredient in registered end-use products, and the limited evidence of any adverse effects. Thus, EPA determined that a quantitative residential exposure risk assessment is not needed for the registered uses of lactic acid.

*Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found lactic acid to share a common mechanism of toxicity with any other substances, and lactic acid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that lactic acid does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to

determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <https://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the lack of threshold effects, EPA has not identified any toxicological endpoints of concern and is conducting a qualitative assessment of lactic acid. That qualitative assessment does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on an assessment of lactic acid, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

#### *E. Aggregate Risks and Determination of Safety*

Because no toxicological endpoints of concern were identified, EPA concludes that aggregate exposure to residues of lactic acid will not pose a risk to the U.S. population, including infants and children, and that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to lactic acid residues.

#### *Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is proposing to establish exemptions from the requirement of a tolerance without any numerical limitation.

## **V. Conclusion**

Therefore, EPA is proposing to remove the duplicative exemption for residues of lactic acid when used in antimicrobial pesticide formulations applied to dairy-processing equipment and food-processing equipment and utensils, and to establish exemptions from the requirement of a tolerance for residues of lactic acid when used as a fruit and vegetable wash in or on all raw agricultural commodities, and for indirect or inadvertent residues of lactic acid in or on all livestock commodities, when residues are present therein as a result of animal drinking water coming into contact with hard non-porous surfaces treated with lactic acid (i.e., troughs).

## **VI. Statutory and Executive Order Reviews**

In this proposed rule, EPA is proposing to establish exemptions from the requirement of a tolerance under FFDCA section 408, and to remove an exemption that is not necessary. The Office of Management and Budget (OMB) has exempted these types of action from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866, due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). Nor does it require any special considerations as required by Executive Order 12898, entitled “Federal

Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This proposed rule does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or revocations might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. These analyses for tolerance establishments and modifications, and for tolerance revocations were published in the **Federal Register** of May 4, 1981 (46 FR 24950) and December 17, 1997 (62 FR 66020) (FRL-5753-1), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. Furthermore, for the pesticide named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposed rule that would change EPA's previous analysis. Any comments about the Agency's determination should be submitted to the EPA along with comments on the proposed rule and will be addressed prior to issuing a final rule.

In addition, the Agency has determined that this proposed rule will not have a substantial direct effect on States, on the relationship between the National Government

and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This proposed rule does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 3, 2023.

**Edward Messina,**

*Director, Office of Pesticide Programs.*

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

### **PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.940, amend paragraph (b) by removing the entry for “Lactic acid” from the table.

3. Revise § 180.1090 to read as follows:

#### **§ 180.1090 Lactic acid; exemption from the requirement of a tolerance.**

(a) Lactic acid (2-hydroxypropanoic acid) is exempted from the requirement of a tolerance when used as a plant growth regulator or fruit and vegetable wash in or on all raw agricultural commodities.

(b) An exemption from the requirement of a tolerance is established for indirect or inadvertent residues of lactic acid (2-hydroxypropanoic acid) in or on all livestock commodities, when residues are present therein as a result of animal drinking water coming into contact with hard non-porous surfaces treated with lactic acid (i.e., troughs).

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